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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,101	06/16/2000	Patrick de Baetselier	4432US	2709

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,101	DE BAETSELIER ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-22* is/are pending in the application.

4a) Of the above claim(s) *4-10,12,14,15,18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *21 and 22* is/are allowed.

6)☒ Claim(s) *1-3,11,16,17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office Action is responsive to Applicant's amendment and response filed February 9, 2004. Claims 1-2, 11, 17 and 20 have been amended. New claims 21-22 have been added.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment the rejection of claim 2 under 35 U.S.C. 112, second paragraph, page 11, paragraph 6 of the previous Office action is withdrawn.

Rejections Maintained

4. The rejection of claims 1-3 and 20 under 35 U.S.C. 102(b) as anticipated by Bilej et al is maintained for the reasons set forth on pages 2-3, paragraph 2 of the previous Office Action.

The rejection was on the grounds that Bilej et al teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity. Bilej et al teach that the coelomic fluid of the earthworm contains strong proteolytic, hemolytic, bacteriolytic and cytolytic factors and may be an ancestral form of TNF-α. It would be inherent that the CCF-1 protein as taught by Bilej et al would comprise at least 9 contiguous amino acids of SEQ ID No: 1 or comprise the amino acid sequence of SEQ ID NO: 3 or a functional fragment thereof.

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the polypeptide of the prior art does not possess the

same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Bilej et al *(March –April 1994)* do not anticipate the claimed invention. Applicant urges that Bilej et al do not disclose an isolated peptide which has from 13 to 60 amino acids and which comprises SEQ ID NO: 1. Applicant urges that Bilej et al disclose a semi-pure active fraction". Applicant urges that the term isolated means that the peptide is separated from other proteins in pure form. Applicant urges that amended independent claim 2 is not anticipated by Bilej et al since Bilej et al do not disclose an isolated or recombinant peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment thereof having trypanolytic activity.

Applicant's arguments filed in February 9, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show why the peptide of the reference is not the same as the claimed peptide. It should be noted that the claims require that the peptides be isolated or recombinantly produced. Bilej et al teach a semi-pure fraction that retains trypanolytic activity. It should be noted that monoclonal antibodies were prepared from the semi-purified fraction of Bilej et al. It is not known in the art to prepare monoclonal antibodies to fractions that are not pure or peptides that have not been isolated. It should noted that there is no limitation recited in the claims that requires that the claimed peptides have a specific level of purity. Applicant has provided no side-by-side comparison to show that

the peptides of the prior art differ from the claimed invention. Therefore, Bilej et al anticipate the claimed invention.

5. The rejection of claims 11 and 16 –17 under 35 U.S.C. 102(b) as anticipated by Bilej et al is maintained for the reasons set forth on pages 3-4, paragraph 3 of the previous Office Action.

The rejection was on the grounds that Bilej et al teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice (see page 124). The composition of Bilej et al is the same as the claimed invention. It would be inherent that the concentrated coelomic fluid sample would contain a peptide comprising at least 9 contiguous amino acids of SEQ ID NO: 1 or a peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment/epitope of either thereof.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best,

Applicant urges that Bilej et al do not disclose a pharmaceutical composition comprising a peptide selected from the group consisting of an isolated peptide which has from 13 to 60 amino acids and which comprises SEQ ID NO:1, an isolated or recombinant peptide comprising SEQ ID NO:3, a fragment of SEQ ID NO: 1 having trypanolytic activity, a fragment of SEQ ID NO: 3 having trypanolytic activity, a epitope of SEQ ID NO:1 or an epitope of SEQ ID NO:3.

Applicant's arguments filed in February 9, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show why the pharmaceutical composition of the reference is not the same as the

claimed pharmaceutical composition. Bilej et al teach a semi-pure fraction that retains trypanolytic activity. It should be noted that monoclonal antibodies were prepared from the semi-purified fraction of Bilej et al. It is not known in the art to prepare monoclonal antibodies to fractions that are not pure or peptides that have not been isolated. Applicant has provided no side-by-side comparison to show that the peptides of the prior art differ from the claimed invention. Therefore, Bilej et al anticipate the claimed invention.

6. The rejection of claims 1 and 3 under 35 U.S.C. 112, first paragraph (written description) is maintained for the reasons set forth on pages 5-7, paragraph 4 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention an isolated peptide comprising at least 9 contiguous amino acids of SEQ ID No: 1. The specification states that "the term fragment of a sequence or part of a sequence means a truncated sequence of the original sequence referred to and that protein sequence can vary widely in length, the minimum size being a sequence of sufficient size to provide a sequence with at least a comparable function and/or activity of the original sequence referred to while the maximum size is not critical" (pages 10-11). The specification states that 'the typically the truncated amino acid sequence will range from about 5 to about 60 amino acids in length (page 11). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants of SEQ ID No:1 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification broadly describes a genus of isolated peptides that have no structural description accompanying the variant language (i.e. comprising at least 9 contiguous amino acids) recited in the claims. While mutagenesis techniques are known

in the art, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the amino acid's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining a certain activity or function are limited in any peptide and the result of such modifications is unpredictable based on the instant disclosure. Therefore, only SEQ ID NO: 1 and not the full breadth of the claim (i.e. an isolated peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that amended claim 1 is directed to an isolated peptide which comprises SEQ ID NO:1 and has 13 to 60 amino acids. Applicant urges that the specification describes amino acid sequences between about 5 to 60 amino acids in length and comprising SEQ ID NO:1 that show the essential characteristics to the whole protein.

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive. Applicant has not provided written description for the genus of peptides claimed. The specification has failed to describe the structure of the claimed fragments or epitopes of SEQ ID NO: 1 and SEQ ID NO:3. The specification only has written description for SEQ ID NO:1 and SEQ ID NO:3. Therefore, only SEQ ID NO: 1 and SEQ ID NO:3 and not the full breadth of the claim (i.e. fragments or epitopes) meet the written description provision of 35 USC 112, first paragraph.

7. The rejection under 35 U.S.C. 112, first paragraph (enablement) is maintained for claims 1-3, 11, 16-17 and 20 the reasons set forth on pages 7-10, paragraph 5 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is enabling only for the peptides of SEQ ID NO:1 and SEQ ID NO:3 and which actually have trypanolytic activity, as disclosed in the specification.

The specification states "that SEQ ID NO:1 comprising 13 amino acids shows essential cytolytic, trypanolytic and glucan-binding characteristics comparable to the whole protein" (page 10). The specification further states " that the peptide termed CCF-1/TIP (represented by SEQ ID NO:1, the trypanolytic domain) was tested in a trypanolytic assay and was found to be trypanolytic in a time and dose-dependent way" (page 17 and Figure 1). The specification does not disclose whether or not SEQ ID NO:3 or fragments or epitopes thereof have cytolytic or trypanolytic activity.

There is no guidance provided as to which amino acids can be deleted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are

conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation. There is no guidance as to what amino acids may not be changed without causing a detrimental effect to the polypeptide being claimed. The claims broadly teach polypeptides which include substitutions and/or deletions, therefore any polypeptide is being claimed, and no specific location for the deletion, substitution or any combination thereof is recited. Thus, the resulting polypeptide could result in a polypeptide not taught nor enabled by the specification.

Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984", (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a Praline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "Protein Structure: A Practical Approach, 1989; pages 184-186" teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Therefore the specification fails to provide guidance regarding as to whether the peptides comprising fragments or epitopes of SEQ ID NO:1 or SEQ ID NO:3 that have cytolytic or trypanolytic activity. One of skill in the art would require guidance, in order to make or use fragments or epitopes of SEQ ID NO:1 or SEQ ID NO:3 in a manner reasonable in correlation with the scope of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting fragments or epitopes having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are fragments or epitopes of SEQ ID NO: 1 or SEQ ID NO:3 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicant urges that the specification discloses that an isolated peptide may have up to 60 amino acids and that the full length CFF-1 has trypanolytic activity. Applicant urges that a peptide which has up to 60 amino acids and comprises SEQ ID NO: 1 would have trypanolytic activity. Applicant urges that an isolated or recombinant peptide comprising SEQ ID NO:3 or a fragment thereof having trypanolytic activity is enabled. Applicant urges that one of ordinary skill in the art would be able to make and use the isolated or recombinant peptides without undue experimentation.

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive. Applicant has not provided enablement for the genus of peptides claimed. The specification has failed to describe the structure of the claimed fragments or epitopes of SEQ ID NO: 1 and SEQ ID NO:3. The statue under 112, first paragraph requires that Applicant teaches how to "make and use" the claimed invention not how to "find" the peptides that meet the limitations recited in the claims. Applicant has provided no structure for fragments or epitopes of SEQ ID NO:1 or SEQ ID NO:3. Therefore, only SEQ ID NO: 1 and SEQ ID NO:3 and not the full breadth of the claim (i.e. fragments or epitopes) meet the enablement requirement provision of 35 USC 112, first paragraph.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 11, 16-17 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to isolated and recombinant peptides which comprise SEQ ID NO: 1 or SEQ ID NO:3 or fragments thereof and pharmaceutical compositions comprising these peptides.

The specification teaches that the peptides of the invention may be useful in tumor therapy, microbial infection, inflammation or immunology (page 1). The specification has failed to teach or disclose how the claimed pharmaceutical compositions can be used to treat all microbial infections and all cancers. The term "pharmaceutical composition " encompasses the ability to treat against infection. The specification does not provide evidence that the claimed pharmaceutical compositions treat any or all microbial infections, all types of cancer or all causes of inflammation. The state of the art regarding a few of the bacterial infections, viral infections or cancers encompassed by the claims is cited below:

Bystryn *(Cancer and Metastasis Reviews, 9:81-18)* teaches that it is difficult to induce the rejection of already established tumors with vaccines (page 83). Bystryn teaches that the ideal cancer vaccine should be safe, effective against a broad range of tumors of the same histological type, sufficiently potent to require only a few immunizations, simple to manufacture in a reproducible manner, and stable for a prolonged period of time. Bystryn teaches that no such vaccine is available (page 83). Bystryn teaches that the most basic requirement for a cancer vaccine is that it contains tumor antigens that can stimulate a strong and clinically effective anti-tumor immune response in humans (page 83). Bystryn teaches that little is known about the identity of such antigens (page 83). Bystryn teaches that most tumor antigens have been defined with monoclonal antibodies that are raised by immunizing animals with human tumor cells, however, the functional effect of the immune responses induced by these antigens is still not known (page 83). Bystryn teaches that for vaccine immunotherapy to be effective, the immune responses induced must be directed to the antigens expressed by the tumor being treated and unfortunately, the pattern of tumor antigens expressed by cancers of the same histological type in different individuals is variable (page 84). Bystryn teaches that there is variation in the pattern of tumor antigens expressed by different tumor nodules in the same individual and by different tumor cells in the same nodule (page 84). Bystryn teaches that it is unlikely that a single tumor antigen will be effective against a broad range of tumors of the same histological type (page 84). Gura *(Science 278:1041-1042, 1997)* teaches that researchers face the problem of sifting

through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile (see first paragraph of page 1041).

It is well known in the art that there are several different antigens from *Moraxella catarrhalis* (i.e. outer membrane proteins and lipooligosaccharides). It is also taught that since infections caused by *Moraxella* predominately occur on mucosal surfaces, the mucosal immune response is likely important as the first line of defense. Mucosal or surface antigen immune response would likely be important in the search for candidate vaccines Kyd et al, *(Vaccine 18 (2000), 398-406))*. It has also been recognized in the art that there is currently no vaccine to prevent Moraxella *catarrhalis* infections because of a lack of good animal models for the diseases, a lack of information about the protective antigens, a lack of *in vitro* correlates to immunity against *Moraxella catarrhalis* in humans and the pathogenic mechanisms and host immune response to the pathogens has yet to be clarified (Samukawa et al, *(The Journal of Infectious Diseases, 2000, 181:1842-5)* and Kyd et al, *(Vaccine 18 (2000), 398-406)*). While studies have been shown that the outer membrane proteins can elicit bacterial antibodies, which promote bacterial clearance, the results have not lead to a predictable vaccine against infections caused by *Moraxella catarrhalis*. A similar situation exists with the development of lipooligosaccharides (LOS) based vaccines against infections caused by *Moraxella catarrhalis* (Gu et al, *Infection and Immunity, May 1998, p. 1891-1897).*

It is well known in the art that *Plasmodium falciparum* is the etiologic agent that causes malaria. Odeh *(Cytokine, April 7;14(1):11-8)* teaches that there is no safe and effective vaccine against malaria (see the Abstract).

Fox (*Biotechnology, Vol. 12, February 1994)* teaches that the quest to develop both preventive and therapeutic HIV vaccines is proving a frustrating enterprise. Fox teaches that there are many themes regarding how to approach developing therapeutic agents against HIV infection. Fox teaches that these themes include the use of cytotoxic T lymphocytes, the use of envelope proteins as vaccines and the use of cytokines to boost the immune system. Fox teaches that despite positive results regarding HIV and AIDS research, no therapy has emerged as a sure winner in the campaign against HIV, not a preventive vaccine nor therapeutic vaccine nor any of the immune-system-boosting treatments. Therefore, the prior art has taught that no "HIV protective epitopes" exist.

The cited prior art references indicate that it would require undue experimentation to formulate and use a successful vaccine against any cancer, *Neisseria gonorrhoeae, Plasmodium falciparum, Moraxella catarrhalis* and HIV infections without the prior demonstration of vaccine efficacy. The prior art cited has established that problems and barriers exist in vaccine development. The above mentioned infections/diseases are only a few of the infections/disorders that are encompassed by the claimed invention and represent a small subset of the many diseases that exist that have no vaccine that is effective in treating and/or preventing such infectious diseases. The specification has not shown a correlation between the claimed trypanolytic peptides and *Neisseria gonorrhoeae, Plasmodium falciparum, Moraxella catarrhalis,* cancer or HIV infections. The claimed invention broadly encompasses any microbial infection or disease caused by any microorganism. The

pharmaceutical compositions as claimed would not provide treatment or prevention against any bacteria, viruses or parasitic organism. The specification has not provided enablement for a pharmaceutical composition that treats any microbial infection or disease or cancer since the examples in the instant specification are devoid of experimental results that demonstrate effectiveness of the peptide against infection or cancer. One skilled in the art would have to possess the knowledge or be provided with sufficient guidance to determine if the claimed pharmaceutical compositions would reach the target microorganisms in order to treat or prevent infection. It would require undue experimentation by one of skill in the art to determine whether the claimed vaccines would be protective against any microbial infections or diseases.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to developing a pharmaceutical composition that would achieve a desire level of success when administered to a patient to treat any microbial infection or disease, 3) there are no working examples which

suggest the desired results of a successful pharmaceutical composition that is to treat any microbial infection or disease or any cancer and 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level).

In view of all of the above, it is determined that the specification has not provided guidance that would enable one of skill in the art to be able to make and use the claimed invention commensurate in scope with the claims. One of skill in the art would require undue experimentation to determine whether the claimed pharmaceutical compositions can be used to protect against any microbial infection or diseases or cancer.

Status of Claims

9. No claims are allowed.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
April 26, 2004

NITA MINNIFIELD
PRIMARY EXAMINER
5/3/04